3.2.2 AFCEE Requirements for Development and Use of Lines of Evidence in Ecological Risk Assessments

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Introduction

Lines of evidence in ecological risk assessments (ERAs) are defined as "[i]nformation derived from different sources or by different techniques that can be used to describe and interpret risk estimates. Unlike the term 'weight of evidence', it does not necessarily imply assignment of quantitative weightings to information" (U.S. EPA, 1998). Lines of evidence include the measurement endpoints, which are calculated ecological hazard quotients and indices, as well as other quantitative measures used to evaluate the potential risk of harm to assessment endpoints. In addition, lines of evidence include the qualitative and the professional judgment elements of an ERA. For the baseline ERA, multiple measurement endpoints are often associated with each assessment endpoint; these measurement endpoint lines of evidence are the basis for structuring the analysis section of this assessment. Therefore, the lines of evidence that will be developed for a baseline ERA are delineated only after the assessment endpoints are selected.

Delineating the lines of evidence, particularly the quantitative measurement endpoints, establishes the study design and the data quality objectives (DQOs) for the baseline ERA. As such, the lines of evidence that will be developed for each assessment endpoint are comprehensively described in site-specific work plans (WPs) and sampling and analysis plans (SAPs) (U.S. EPA, 1997).

Preparation of the risk characterization of the ERA includes evaluation and interpretation of all lines of evidence both quantitative and qualitative. The risk characterization, along with the associated uncertainties, is developed such that the thresholds for effects on assessment endpoints and the likelihood of risk of harm to assessment endpoints are understood by the risk managers so that they can make informed and sound decisions.

AFCEE Requirements

The results of screening ecological risk calculations (U.S. EPA, 1997) are likely to be the only quantitative line of evidence to support the decisions that are made at the screening stage. However, additional lines of evidence will be developed using existing and readily available information to more fully inform the decision makers as they determine whether (1) the ecological risk posed by a site is acceptable, and therefore remediation is not required based on ecological risk, or (2) a site may pose potential adverse ecological effects, and therefore a more thorough assessment or, in some cases, immediate remedial action is warranted. In cases where the potential for ecological impacts exists, the available lines of evidence will be used to eliminate negligible-risk combinations of contaminants and exposure pathways from further consideration (U.S. EPA, 1997).

If the outcome of the screening ERA results in a decision that a more thorough assessment is warranted, the lines of evidence that will be used to evaluate the potential risk to site-specific assessment endpoints will be delineated in the WP and the SAP for

the site. Development of the WP and SAP will incorporate the DQO process to ensure that the type, quantity, and quality of data collected for each line of evidence during the ecological investigation are adequate to support the intended use of the information.

In the risk characterization section of the ERA, data from the lines of evidence will be integrated into a statement about risk to the assessment endpoints established during problem formulation. The statement will accomplish the following:

- Interpret the quantitative risk estimate for each assessment endpoint to include existing impacts, risks, and thresholds of effects on the assessment endpoints
- Evaluate the likelihood of the potential adverse effects actually being realized by the assessment endpoints

Although not specifically lines of evidence, the risk characterization section will include information on the following to facilitate the making of fully informed decisions:

- The location and areal extent of contamination above a threshold for adverse effects
- The degree to which the contaminant concentration exceeds the threshold for adverse effects
- The duration that the contaminant concentrations are expected to exceed the threshold for adverse effects, both with and without removal of the contaminant source

Recommended Practices and Guidance

The development, presentation, and interpretation of the lines of evidence should be done such that a framework is developed for expressing the confidence in the estimate of risk to the assessment endpoints. The lines of evidence are not intended to provide the "proof" demanded in experimental work. However, the risk assessor needs to provide a comprehensive evaluation of all of the lines of evidence developed in the ERA. Presenting only the numeric outcomes of the measurement endpoints will not provide adequate information for the decision-making process.

Confidence in the evaluated risk of harm to assessment endpoints will be increased substantially if several lines of evidence—derived from different sources and techniques—are used in the evaluation. Such lines of evidence include hazard quotients and indices, additional quotient estimates (for example, calculated using background concentrations of chemicals of potential ecological concern), modeling results, bioassays, field information (including the status of vegetation from contaminated and reference areas, abundance and diversity of macroinvertebrates, and species activity observations), extent and mobility of the contamination, tissue data from public health evaluations, and chemical-specific applicable or relevant and appropriate requirements.

When lines of evidence are used to facilitate interpretation of the risk assessment outcome, three factors must be considered when evaluating the information.

- The quality of the data for each line of evidence needs to be delineated. If the information is qualitative, the identity and credentials of the professional interpreting the information should be provided

- The uncertainty associated with each line of evidence should be described
- The directness with which each line of evidence relates to the questions or hypotheses defined during problem formulation should be delineated

After the quality of the collected data, its associated uncertainty, and its relationship to the risk hypotheses have been delineated, a line of evidence is described and interpreted. If lines of evidence do not point toward the same conclusion, the reasons for any inconsistencies should be investigated and discussed in the risk characterization section. If possible, any inconsistencies should be explained to provide an overall conclusion of the potential risk to assessment endpoints, thus providing clear useful information to the decision makers.

References

U.S. EPA. 1997. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final*. U.S. Environmental Protection Agency: EPA/630/R-95-002F.

U.S. EPA. 1998. *Guidelines for Ecological Risk Assessment, Final.* U.S. Environmental Protection Agency: EPA/540/R-97-006.